AUG 2 8 2008

CardinalHealth

K081464

SUMMARY OF SAFETY AND EFFECTIVENESS
As required by §807.92(c)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Latex Sterile Exam Powder Free Gloves

Regulatory Affairs Contact:	Steve Tamsett Cardinal Health 1500 Waukegan Road McGaw Park, IL 60085
Telephone:	(847) 578.2325
Fax:	(847) 689-2715
Date Summary Prepared:	8/28/08
Product Trade Name:	Sterile Latex Powder Free Exam Gloves
Common Name:	Exam Glove
Classification:	Glove, Exam LYY
Predicate Devices:	Cardinal Health's Powder-Free Latex Exam Gloves (K024292)
Description:	Latex Exam Gloves are formulated using Natural Rubber Latex. The device is offered powder-free and sterile.

Intended Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

CardinalHealth

SUMMARY OF SAFETY AND EFFECTIVENESS
As required by §807.92(c)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Substantial Equivalence:	Sterile Latex Exam Gloves are substantially equivalent to Latex Powder-Free Exam Gloves in that they provide the following characteristics: - Same intended use - Same sizes, product features - Both made of Natural Rubber Latex using the same manufacturing processes

Summary of Testing:

Test	Result
Primary Skin Irritation	Gloves are non-irritating.
Guinea Pig Maximization	Gloves do not display any potential for sensitization.
Ultimate Elongation	Gloves meet requirements for latex exam rubber gloves per ASTM D 3578
Tensile Strength	Gloves meet requirements for latex exam rubber gloves per ASTM D 3578
Barrier Defects	Gloves meet requirements per 21 CFR Section 800.20 AQL = 4.0 and ASTM D 3578, AQL = 2.5. Cardinal Health internal AQL is 1.5
Data/Test Method	Gloves meet powder level requirements for "Powder Free" designation using ASTM Standard D 6124-*Standard test method for residual powder on medical gloves.* Results generated values below 2 mg of residual powder per glove.

Packaging Integrity:

Packaging was tested following ANSI, AAMI, ISO 11607-1, Part 1, Packaging for terminally sterilized medical devices-Part1, and ANSI, AAMI, ISO 11607-2, Part 2, Packaging for terminally sterilized medical devices-part-2, requirements for materials, sterile barrier systems and packaging systems.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 8 2008

Mr. Steve Tamsett
Regulatory Affairs Manager
Cardinal Health
1500 Waukegan Road
McGaw Park, Illinois 60085

Re: K081464
Trade/Device Name: Sterile, Latex, Powder-Free Exam Gloves
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYY
Dated: August 22, 2008
Received: August 26, 2008

Dear Mr. Tamsett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CardinalHealth

Statement Indications for Use

510(k) Number: (if known): To be Assigned

Device Name: Sterile, Latex, Powder-Free Exam Gloves

Indications For Use:

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner

Prescription Use _____ AND/OR Over-The Counter Use __X___
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K 081464